K061735
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Section E: 510(K) Summary

Applicant:
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SEP - 8 2006

Contact person : Andrea Ratti

Device Trade Name InFibra

Device Common Name Fiber reinforcement material

Device Classification Name Class II - Denture realigning, repairing or rebasing resin (CFR 872.3760)

Product code: EBI

Description of Device
InFibra is a fiber reinforcement used to reinforce dental resins. It is made of ultra-high-molecular-weight polyethylene (UHMW). The fibers are braided and not leno-weave treated.

Performance Standards & Testings
Standard ISO 10993 – 5 "Biological evaluation of medical devices – Tests for cytoxicity: in vitro methods" was conducted and show no evidence of cytotoxic response.
Mechanical Tests were conducted in conformance with ISO 3597-2 (Three point Bending standards). The results showed the material to be suitable for reinforcing 1) removable dentures 2) crown and bridges 3) provisional crown and bridges 4) splint device reinforcement 2) splinting of teeth 6) orthodontic appliances
Other mechanical tests were conducted to characterize the material.

Predicate device - Substantial Equivalency
The modified is substantially equivalent to the previously Ribbond TM (K 913040 date 7 October 1991) and EZ Connect (K 000346)
The modified device is substantially equivalent in quality of mechanical characteristics, of mechanical safety, of materials, of design, of performance and of indication for use.

Description of new characteristics
InFibra is made of UHMW fiber braided. Tests show that InFibra has greater load carrying capacity than the leno-weave.
The different design characteristics of InFibra are primary differences of minor changes to the materials and dimensions and does not raise new questions of safety and effectiveness and demonstrates that the device is as safe and effective as the predicate device.
There are no new hazards presented with InFibra as with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2006

Bioloren sas
C/O Mr. Jerry Bartick
President
Global Dental Products, Incorporated
1028 Mclean Avenue
Wantagh, New York 11793

Re: K061735
Trade/Device Name: InFibra
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: June 10, 2006
Received: June 20, 2006

Dear Mr. Bartick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061735

Device Name: Infibra

Indications for Use:

Infibra is intended for use by dentists to provide reinforcement to acrylic or composite resins used for dental restorations. It can be used for the following applications:

As reinforcement in manufacturing and/or repairing full or partial dentures as well as overdentures, night-guards and orthodontic appliances.

To repair and reinforce resin or composite prostheses including temporary and permanent bonded and removable bridges.

To reinforce splints used to immobilize teeth.
Prescription Use X__

(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
(510(k) Number: K061735